

Internal Revenue Service

Department of the Treasury

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Date 12-17-96

Washington, DC 20224

Surname [REDACTED] *1F*

[REDACTED]  
Person to Contact: [REDACTED]

Telephone Number: [REDACTED]

Refer Reply to: CP:E:EO:T:4

Date: **AUG 14 1996**

Employer Identification Number: [REDACTED]

Key District: Northeast (Brooklyn)

Dear Applicant:

We have considered your application for recognition of exemption from federal income tax under section 501(a) of the Internal Revenue Code as an organization described in section 501(c)(3). Based on the information submitted, we have concluded that you do not qualify for exemption under that section. The basis for our conclusion is set forth below.

You were incorporated in the State of [REDACTED] on [REDACTED]. Your amended articles of incorporation provide that you are organized exclusively for charitable, religious, educational, and scientific purposes.

On your Form 1023 and subsequent submissions you state that your activities will be to:

1. conduct clinical trials with HIV positive and AIDS patients and high risk volunteers according to conventional as well as alternative forms of medicine;
2. conduct research and development in the field of BIV/AIDS vaccine; and
3. receive donations from HIV positive and AIDS patients, high risk volunteers, AIDS organizations, governments and hospitals.

In a letter dated [REDACTED], you state that you have tested the BIV vaccine on [REDACTED] patients. The sole purpose of your activity will be limited to vaccinating voluntary AIDS patients. You state that the vaccine in limited quantity will be produced at minimum cost and given to patients for a fee, but without any profit. Your creator devotes 12 to 18 hours per day learning more about AIDS, collecting literature and conducting theoretical and basic research in your laboratory. As part of his studies to learn more about AIDS, he has visited foreign countries and universities.

[REDACTED]

Your creator has filed a patent on the vaccine you are testing. If the patent is issued, it will eventually be licensed to private industry for production and marketing. If there are patent royalties, you state that they will be paid to your creator. The content of the patent has been published in the World Intellectual Property Organization: Human AIDS Vaccine From Cattle AIDS Virus. Your founder and creator has also had his theories published in scientific publications and you represent that you will publish the results of his research.

You are also currently pursuing Food and Drug Administration (FDA) certification for human trials of your vaccine. At the same time, you are seeking approval for vaccine testing from the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), that has the major responsibility in the federal government for basic and clinical research on AIDS.

Your board of directors is currently composed of four persons, at least three of whom are related. You propose to expand your board with members of the [REDACTED] University and medical community after the AIDS vaccine proves to be effective. You state that [REDACTED] (daughter of your creator) will be granted lifetime tenure as president and chairperson of the board or until such time as she chooses to remove herself from either position and allows the board to appoint her successor(s). She also has veto power over decisions made by your board. [REDACTED] (your creator and inventor of the BIV vaccine) will be granted lifetime tenure as vice president and executive director of the board or until such time as he chooses to remove himself from either position and allows the board to appoint his successor(s). The [REDACTED] family has invested nearly \$[REDACTED] in cash in your AIDS vaccine project.

You are operating both human clinical and animal research in a laboratory that you rent from your creator at [REDACTED] Street. Your founder and his wife also live at this address. According to your lease agreement, you pay \$[REDACTED] per month plus utilities, telephone and other expenses. The rent is to be considered as a loan by your landlord. Any reimbursement will be made from your contribution fund.

Section 501(c)(3) of the Code provides for the exemption from Federal income tax of organizations that are organized and operated exclusively for charitable, scientific, educational, or testing for public safety purposes.

Section 1.501(c)(3)-1(d)(1)(ii) of the Income Tax Regulations provides that an organization is not organized or operated exclusively for exempt purposes unless it serves a

public rather than a private purpose. To meet this requirement, it is necessary for an organization to establish that it is not organized or operated for the benefit of private interests.

Section 1.501(c)(3)-1(d)(4) of the regulations defines the term "testing for public safety" as used in section 501(c)(3) to include the testing of consumer products, such as electrical products, to determine whether they are safe for use by the general public.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations in defining the term "scientific" provides that since an organization may meet the requirements of section 501(c)(3) only if it serves a public rather than a private interest, a scientific organization must be organized and operated in the public interest.

Section 1.501(c)(3)-1(d)(5)(ii) of the regulations provides that scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations, as, for example, the ordinary testing or inspection of materials or products.

Section 1.501(c)(3)-1(d)(5)(iii) of the regulations states that scientific research will be regarded as carried on in the public interest --

(a) If the results of such research (including any patents, copyrights, processes, or formulae resulting from such research) are made available to the public on a nondiscriminatory basis;

(b) If such research is performed for the United States, or any of its agencies or instrumentalities, or for a State or political subdivision thereof; or

(c) If such research is directed toward benefiting the public. The following are examples of scientific research which will be considered as directed toward benefiting the public, and therefore, which will be regarded as carried on in the public interest: (1) Scientific research carried on for the purpose of aiding in the scientific education of college or university students; (2) scientific research carried on for the purpose of obtaining scientific information, which is published in a treatise, thesis, trade publication, or in any other form that is available to the interested public; (3) scientific research carried on for the purpose of discovering a cure for a disease; or (4) scientific research carried on for the purpose of aiding a community or geographical area by attracting new industry to the community or area or by encouraging the development of, or retention of, an industry in the community or area. Scientific

research described in this subdivision will be regarded as carried on in the public interest even though such research is performed pursuant to a contract or agreement under which the sponsor or sponsors of the research have the right to obtain ownership or control of any patents, copyrights, processes, or formulae resulting from such research.

Section 1.501(c)(3)-1(d)(5)(iv) provides that an organization will not be organized and operated for the purpose of carrying on scientific research in the public interest and consequently will not qualify under section 501(c)(3) as a scientific organization if --

(a) Such organization will perform research only for persons which are (directly or indirectly) its creators and which are not described in section 501(c)(3).

Rev. Rul. 65-1, 1965-1 C.B. 226, describes an organization which promotes and fosters the development and design of machinery in connection with commercial operations, and in connection therewith has the power to sell, assign, and grant licenses with respect to its copyrights, trademarks, trade names, or patent rights. The revenue ruling concludes that the organization does not qualify for exemption from federal income tax under section 501(c)(3) of the Code as a scientific organization because its activities were incident to a commercial operation and did not constitute scientific research within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations. See also Rev. Rul. 76-296, 1976-2 C.B. 142 and 78-426, 1978-2 C.B. 175.

Rev. Rul. 68-373, 1968-2 C.B. 206, describes a nonprofit organization primarily engaged in testing drugs for commercial pharmaceutical companies. The revenue ruling concludes that the organization does not qualify for exemption under section 501(c)(3) of the Code because the testing is merely a service performed for the manufacturer rather than testing for public safety. Such testing principally serves the private interests of the manufacturer rather than the public interest.

Under the facts described, your organization appears to be providing a benefit to the public by engaging in research to find a cure for AIDS and publishing the results of your studies. However, because your creator controls your organization directly and indirectly through his position on the board of directors and the positions of members of his family (including his daughter's veto power) it appears that you principally serve the private interest of your creator rather than a public interest. Thus, you are not operated for the purpose of carrying on scientific

research in the public interest. See sections 1.501(c)(3)-1(d)(1)(ii) and 1.501(c)(3)-1(d)(5)(iv)(a) of the regulations, supra.

In addition, you appear to be similar to the organization in Rev. Rul. 68-373, supra. Your principal activity is conducting clinical trials aimed at securing approval of the BIV vaccine by the FDA. These trials are required in order to comply with Food and Drug Administration requirements that drugs be tested for safety and efficacy before they can be marketed.

Until a drug is approved for marketing by the Food and Drug Administration, it is not a "consumer product," available for general use by the public. The clinical testing of the BIV vaccine for safety and efficacy in order to enable your creator to meet FDA requirements for marketing is not testing for public safety but is merely a service performed for your creator. Such testing principally serves the private interest of your creator rather than the public interest.

Therefore, you are not exempt from federal income tax as an organization operated for the purpose of testing for public safety because you serve private, rather than public interests.

Accordingly, you do not qualify for exemption as an organization described in section 501(c)(3) of the Code and you must file federal income tax returns.

Contributions to you are not deductible under section 170 of the Code.

You have the right to protest this ruling if you believe it is incorrect. To protest, you should submit a statement of your views, with a full explanation of your reasoning. This statement, signed by one of your officers, must be submitted within 30 days from the date of this letter. You also have a right to a conference in this office after your statement is submitted. You must request the conference, if you want one, when you file your protest statement. If you are to be represented by someone who is not one of your officers, that person will need to file a proper power of attorney and otherwise qualify under our Conference and Practices Requirements.

If you do not protest this ruling in a timely manner, it will be considered by the Internal Revenue Service as a failure to exhaust available administrative remedies. Section 7428(b)(2) of the Code provides, in part, that a declaratory judgement or decree under this section shall not be issued in any proceeding unless the Tax Court, the United States Court of Federal Claims, or the District Court of the United States for the District of

[REDACTED]

Columbia determines that the organization involved has exhausted administrative remedies available to it within the Internal Revenue Service.

If we do not hear from you within 30 days this ruling will become final and copies will be forwarded to your key district office. Thereafter, any questions about your federal income tax status should be addressed to that office. The appropriate State Officials will be notified of this action in accordance with Code section 6104(c).

When sending additional letters to us with respect to this case, you will expedite their receipt by using the following address:

Internal Revenue Service  
Attn: CP:E:EO:T:1-SC, Room 6514  
1111 Constitution Ave, N.W.  
Washington, D.C. 20224

If you have any questions, please contact the person whose name and telephone number are shown in the heading of this letter.

Sincerely,

(signed) [REDACTED]

[REDACTED]  
Chief, Exempt Organizations  
Technical Branch 1

cc: DD, Northeast Key District Office (EP/EO)  
Information Copy: Chief, EP/EO Division

cc: All state officials